Sub, File

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 11, 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Mancozeb (014504). Reregistration Case No. 0643
Mancozeb Task Force Protocol-Field Trials on Field Corn, Sweet Corn, Cucumbers, Potatoes, Tomatoes, and Squash. Crop Group Tolerance proposal for Cucurbits
[No MRID No.; CB 15456; DP BARCODE: D214382]

FROM: Susan V. Hummel, Acting Section Head
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

TO: Judy Loranger/Linda Propst, PM#73
Reregistration Branch
Special Review & Reregistration Division [7508W]

The Mancozeb Task Force has submitted a proposal to comply with the outstanding residue data requirements for Field Corn, Sweet Corn, Cucumbers, Potatoes, Tomatoes, and Squash, as presented in an Apr 13 meeting with the Task Force. Their proposal includes consideration of a Crop Group Tolerance proposal for Cucurbits. Mancozeb is on List A. A Registration Standard was issued 3/87, with the Residue Chemistry Chapter completed 9/10/86, and several updates issued subsequently. A Reg. Std. Update was completed 8/11/92, with a review of a Rohm and Haas response to the Update completed 9/1/93 (S. Hummel, CB 11286, DP Barcode D187395). A DCI for the Mancozeb Residue Chemistry data requirements has not been sent yet. A petition proposing establishment of a tolerance for mancozeb on cucurbits is in reject status (PP#3E4173, R. Lascola, 5/26/93, CB 11026, D185414, D185417). The review noted that additional data were required per the Mancozeb Update of 8/11/92.

The Task Force proposal includes the slides presented at the 4/13/95 meeting, the data requirements as stated in the 8/11/92 Update, the data requirements for each crop as stated in the 6/94 updated guidance on Number and Location of Field Trials, the number and location of existing Mancozeb Field trials, the difference between the number and location of field trials as required in the 6/94 guidance, and their proposal for the number and location of trials which they will conduct. Justification for providing fewer than the number of trials required in the 6/94 updated guidance was provided. Summaries of existing

mancozeb data prepared for submission to CODEX were included for some of the crops included in this protocol, and for others not included in the protocol. The Mancozeb Task Force requested responses to four questions. The responses to their questions will be included in our conclusions below.

Conclusions

1. Does the Agency concur that no additional residue decline studies are needed for these five crops?

   Response: Yes. No additional decline data are needed for these five crops. However, additional decline data may be needed for other crops.

2. Does the Agency concur that no additional storage stability studies are needed for these five crops if samples are analyzed within 30 days of harvest.

   Response: No. Provided the laboratories participating in this study do not change, no additional storage stability studies will be needed for these five crops, provided samples are analyzed within 2 weeks of harvest. If samples are held more than 2 weeks after harvest, concurrent storage stability studies will be needed.

3. Does the Agency concur with the location and number of residue trials the Task Force is proposing to conduct for these five crops?

   Response: Not completely. The number and location of field trials proposed by the Mancozeb Task Force are acceptable for field corn, cucumbers, and tomatoes. Additional field trials beyond those proposed are needed for sweet corn, melons, summer squash, and potatoes.

   At least three field trials for sweet corn must be conducted in Region V, in areas where 15 applications are permitted.

   Upon reviewing the amount of residue data available for melons (both cantaloupe and watermelon), we have determined that there are insufficient data. At least four additional trials must be conducted, one in Region II, one in Region V, and two in Region X.

   At least one additional field trial must be conducted for summer squash in Region VI.

At least two field trials are needed for potatoes in Region XI. The field trials in Region V should be conducted using the 3 day PHI.

4. Does the Agency concur with the Task Force proposal to conduct residue studies for summer squash? (The Task Force would like to pursue a crop group tolerance which will involve squash data.)

   Response: Included in the response to Question III.

5. Although the three reasons cited by the Mancozeb Task Force for reducing the required number of field trials did not provide adequate justification, in reassessing the field trial data requirements, all available data were considered, including those from use patterns similar, but not exactly the same as, the PD 4 use pattern. Reasons cited for reducing the number of field corn trials was persuasive, considering that sweet corn had a more extreme use pattern (and assuming that adequate data would be available for sweet corn).

Recommendations

We recommend that the data requirements for field corn, sweet corn, tomatoes, cucumbers, melons, summer squash, and potatoes be modified as described in this review. We recommend that a copy of the entire review be provided to the registrant.

Detailed Considerations

Rationalization for reduction in the number of field trials

The Mancozeb Task Force cites several reasons why they should not be required to perform the total number of field trials specified in the 6/94 Guidance on Number and Location of Field Trials.

1. The 6/94 Guidelines allow for a 25% reduction in the number of field trials when a tolerance is established and the use pattern is being amended.

2. The stated criteria for the number of field trials included consideration of the acreage of the crop. A high acreage is required for grain crops, such as wheat and corn. However, the percent of the grain crops treated with mancozeb is very low, 1% on field corn, and 6% on sweet corn.

3. The stated criteria for the number of field trials included consideration of the dietary consumption of the crop, such that four additional trials were required for tomatoes. The Task Force presumes that the additional trials were required to obtain a better estimate of field residues for use in exposure assessment. However, the residue data required for the five crops which are the subject of this review will be used only for tolerance setting, and not for dietary risk assessment, because the dietary risk assessment was already conducted using market basket survey data. Thus, the four additional trials for tomatoes are not needed for dietary exposure assessment.

CBRS Comment

Fewer field trials needed for amended registrations. The allowance for fewer field trial needed to support amended registrations assumes that there are adequate residue data supporting the previously registered use pattern(s). This is not the case for mancozeb. Additional field trial data were required to support use of the WP/F1C formulation of mancozeb in the Registration Standard for all five of the crops except field corn. Data for sweet corn were only required for OR/WA. Although the Registration Standard did not specify the number of field trials required for each geographic region (state), guidance available at that time stated that the number of field trials should be proportional to the production in each growing area and that there should be a sufficient number of trials. Thus, with the exception of field corn, no reduction in the number of field trials is justified for consideration as an amended registration.

Acreage of the crop. The primary basis for the number of field trials required was the acreage of the crop grown, as a measure of the importance of the crop in agriculture. The percent of crop treated will not be taken into account in determining the number of trials. This is not a justifiable reason for lowering the number of field trials required.

Dietary Significance/Dietary Exposure Data. One of the stated criteria for the number of field trials was the dietary significance of the crop. A larger number of field trials would be required for crops of greater dietary significance. The primary reason for this was the importance of having the tolerance set properly for crops of greater significance in the diet. This would better avoid tolerance exceeding residues by better determining the proper tolerance level. This is

independent of the secondary use of tolerance data for dietary exposure assessment. This is not a justifiable reason for lowering the number of field trials required.

Totality of the Available Database. This was not mentioned as a justification for requiring fewer than stated number of field trials, but we will consider all available mancozeb data, not just the data exactly matching the use pattern required by PD 4. We still need a reasonable amount of data matching the PD 4 use pattern. In general, the Task Force proposal for numbers and locations of additional field trials to be conducted should provide sufficient data to regulate mancozeb and ETU.

Additional comments are provided in the sections below dealing with individual crops.

Replicate Samples

The Task Force agrees to collect replicate samples for all new field trials, as specified in the 6/94 Guidance.

Storage Stability Data

The Mancozeb Task Force proposes to analyze all samples within 30 days and not conduct any additional storage stability studies. They cite our recent Guidance for Storage Stability data stating that storage stability data are not required for samples stored less than one month, and that concurrent storage stability studies are not always required, provided that the residues are found to be stable in the matrices of interest, and that storage stability data are available for the same conditions as those used for storage of field trial samples.

CBRS Comment

Our 1/93 updated Guidance on Storage Stability states that storage stability data will not be needed for samples stored frozen for <30 days, unless a pesticide/residue of concern is otherwise known to be volatile or labile (emphasis added). There have been documented storage stability problems with both EBDC and ETU residues in stored crop samples, particularly with potatoes, where residues of the EBDCs and ETU both declined to less than 50% recovery within 2 to 4 weeks. It has now been five years since the storage stability studies were conducted for the EBDC/ETU Market Basket Survey, long enough that those storage stability studies cannot be considered to have been conducted in the same general time frame as the field trials which will be initiated this year. With the history of the laboratories participating in this study, we could agree that no additional storage stability data would be needed, provided all samples were

analyzed within 2 weeks of collection and the samples were stored whole until analysis.

Residue Decline Data

The Task Force provided a tabulation of the number of residue decline studies available for a number of crops.

Crop	Number of decline studies	
Apples	1	
Celery	5	
Corn, field	1	(2 with stalks)
Corn, sweet	6	
Cranberries	5	
Cucumbers	4	
Grapes	7	
Melons	7	
Onions	7	
Papaya	2	
Pears	3	
Sugar Beet, roots	8	
Sugar Beet, tops	2	
Squash, summer	7	
Squash, winter	2	
Tomato	5	

A total of 74 decline studies have been conducted for mancozeb. Mancozeb residues decline after treatment, generally with a half life of 7~9 days. There are no decline data for asparagus, bananas, barley, oats, rye, wheat, fennel, peanuts, or potatoes. For asparagus, cotton, peanuts, potatoes, and the small grains, the Task Force expects very low residues, and expects that decline studies would not provide meaningful data. They note that banana pulp is not exposed to the mancozeb, and therefore no residues are expected. Additionally, celery is similar to fennel, and corn stalks and fodder are similar to straw of the small grains.

CBRS Comment

We agree with the Mancozeb Task Force that no additional decline studies are needed for the five crops included in this proposal. The Task Force may wish to note, however, that the decline data were very useful for estimating residue for use patterns for which residue data were not available. A decline study on bananas may be useful; detectable residues are expected on the whole fruit, which is the regulated commodity, but proposals for banana field trials have not been submitted.

Task Force Proposals by Crop

The Mancozeb Task Force Proposals are presented below by crop in tabular form, using the same terms used by the Task Force:

Required Trials=number of trials required in 6/94 Guidance

Adequate Trials=number of trials considered adequate in the 8/11/92 Update

Needed Trials=number of trials still needed by subtracting the number of adequate trials from the number of required trials.

Needed per Update=number of trials required in 8/11/92 Update

Proposal=number of trials proposed to be conducted by the Task Force

Conclusion=number of trials needed after considering all available data and other factors (CB Conclusions)

Field Corn

Use: 10 x 1.2 lb ai/A, 40 day PHI
Tolerances: 0.1 ppm grain, 5 ppm forage and fodder

REGION	I	II	V	VI	TOTAL
Required	1	1	17	1	20
Adequate	0	0	0	0	0
Needed	1	1	17	1	20
Needed per Update	0	0	5	0	5
Proposal	0	0	5	0	5
Conclusions	**0**	**0**	**5**	**0**	**5**

The Task Force proposes to conduct fewer trials than indicated in the 6/94 Guidance; and to conduct a processing study at 5x, analyzing starch, crude oil, and refined oil from wet milling; and grits, meal, flour, crude oil, and refined oil from dry milling of corn. Their justification for fewer number of trials is the limitation of use to hybrid seed corn, the expectation of non-detectable residues because the corn is treated before the cob or kernels have formed, and the higher number of applications and lower PHI for sweet corn. The limitation to use on hybrid seed corn and the presumed availability of adequate data on sweet

corn from a more extreme use pattern are justifiable reasons for reducing the number of trials needed for field corn, provided a full set of data are available for sweet corn.

Sweet corn

Use: 5 x 1.2 lb ai/A, 7 day PHI west of the Mississippi
15 x 1.2 lb ai/A, 7 day PHI east of the Mississippi

Tolerance: 0.5 ppm on popcorn grain, fresh corn (incl. sweet corn K+CWHR), 5 ppm on forage and fodder

REGION	I	II	III	V	X	XI	XII	TOTAL
Required	2	1	1	5	1	1	1	12
Adequate	1	0	0	2	0	0	1	4
Needed	1	1	1	3	1	0	1	8
Needed per Update	1	0	1	1	0	1	1	5
Proposal	1	0	1	1	1	1	0	5
Conclusions	**1**	**0**	**1**	**3**	**1**	**1**	**0**	**7**

The low percent of crop treated does not justify reducing the number of field trials. Although low or non-detectable residues would be expected on the corn kernels, finite residues are expected on the forage and fodder. As explained in the 6/94 Guidance, a 25% reduction in the number of field trials will be acceptable only if all samples have non-detectable residues.

CUCURBITS: Cucumbers, Melons, Squash

Use: 8 x 2.4 lb ai/A, 5 day PHI
Tolerance: 4 ppm
CUCUMBERS

REGION	II	III	V	VI	X	TOTAL
Required	3(2)	1	2(1)	1	1	8(6)
Adequate	0	2	1	1	0	4
Needed	3(2)	0	1(0)	0	1	5(3)
Needed per Update	1	0	0	0	1	2
Proposal	2	0	0	0	1	3
Conclusions	**2**	**0**	**0**	**0**	**1**	**3**

MELONS (cantaloupe or watermelon)

REGION	II	III	V	VI	X	TOTAL
Required	1/2	0/2(1)	1/1(0)	2(1)/2	4(3)/1	8(6)
Adequate	0	3	0	1	0	4
Needed	1-2	0	0-1	0-1	1-3	5(4)
Needed per Update	0	0	0	0	0	0
Proposal	0	0	0	0	0	0
Conclusions	**1**	**0**	**1**	**0**	**2**	**4**

SUMMER SQUASH

REGION	I	II	III	V	VI	X	XI	TOTAL
Required	1	2(1)	1	1	1	1	1	8(6)
Adequate	0	2(1)	2(1)	2	0	0	0	6(4)
Needed	1	1(0)	1(0)	0	1	1	1	5(3)
Needed per Update	0	0	0	0	1	1	0	2
Proposal	1	0	0	0	0	1	0	2
Conclusions	**1**	**0**	**0**	**0**	**1**	**1**	**0**	**3**

The two field trials in Region II are in the same location and thus count as only one trial. The two field trials in Region III are in the same location and thus count as only one trial. This includes consideration of winter squash data. No winter squash data are available from Region VI. Conclusions on number of field trials include a reduction of 25% for a crop group tolerance.

Potatoes

Use: 7 x 1.6 lb ai/A, 3 day PHI in CT, DE, FL, ME, MI, MA, NY, PA, RI, VT, WI, and 14 days elsewhere
Tolerance: 1 ppm interim tolerance

REGION	I	II	III	V	IX	X	XI	TOTAL
Required	2	1	1	4	1	1	6	16
Adequate	0	0	0	1	0	0	3	4
Needed	2	1	1	3	1	1	3	12
Needed per Update	1	0	0	1	1	0	2	5
Proposal	2	0	2	3	1	1	0	8
Conclusions	**2**	**0**	**2**	**3**	**1**	**1**	**2**	**10**

Justification for no additional field studies in Region XI was that no detectable residues were found at a 15x rate, with a one day PHI, in a previous study, that only 4% of potatoes are grown in Region II, and the claim that the potatoes are not exposed to the mancozeb spray. However, the potatoes could be exposed to mancozeb during harvest. Field trials will not be required in Region II. In Region XI, the PD 4 required a PHI of 14 days. This may change the possibility for residues at harvest. Two field trials in Region XI are needed. The field trials in Region V should be conducted using the 3 day PHI.

Tomatoes

Use: 4 x 1.6 lb ai/A, 5 day PHI west of the Mississippi
7 x 2.4 lb ai/A, 5 day PHI east of the Mississippi
Tolerance: 4 ppm

REGION	I	II	III	V	X	TOTAL
Required	1	1	2	1	11	16
Adequate	0	0	0	0	11	11
Needed	1	1	2	1	0	5
Needed per Update	0	0	1	0	0	1
Proposal	1	1	2	1	0	5
Conclusions	**1**	**1**	**2**	**1**	**0**	**5**

No additional field trials will be required in CA, although some of the cited 11 field trials may have been conducted in the same location.

cc:RF, circu, Mancozeb RSF, Mancozeb SF
RDI:MSM:05/11/95:FBS:05/11/95
7509C:RM:804:CM#2:SVH:svh:x5-7689:05/11/95